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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/632,806	08/04/2000	Lise Thibodeau	045636-5039	2513

9629 7590 07/15/2004

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EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/632,806	Applicant(s) THIBODEAU ET AL.	
	Examiner Jeffrey S. Parkin, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Serial No.: 09/632,806
Applicants: Thibodeau, L, and C. Lavallee

Docket No.: 045636-5039
Filing Date: 08/04/00

Response to Amendment

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the amendment filed 26 April, 2004, wherein claims 1-14 were cancelled. Claims 15-23 are currently under examination. Prosecution on the merits of this application is reopened on claims 15-23 considered unpatentable for the reasons indicated below.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 15-20 and 23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lavallée and Thibodeau (1996) in view of Alving and Glenn (1999). Lavallée and colleague disclose the preparation of recombinant expression constructs encoding modified HIV-1 envelope glycoproteins. Specifically, the V3 loop, with the exception of the GPGRAP crown, was deleted. The resultant construct encodes an HIV-1 Env with the two basal cysteines adjacent to the GPGRAP crown (see Figure 1, p. 984, *Expériences et résultats*, pp. 984-986). The immunogenicity of this protein was also clearly demonstrated by immunoprecipitation experiments with HIV-1-infected patient antisera (see Figure 3, p. 986). The only limitation of this teaching is that it does not disclose art-recognized immunogenic compositions comprising the modified viral envelope and a pharmaceutically acceptable carrier.

However, Alving and colleague (1999) provide a detailed accounting of the preparation of immunogenic compositions comprising unilamellar liposomes and antigens that are capable of inducing strong humoral and cellular immune responses to the immunogen of interest. The preparation of liposomes has been well-documented in the art (see col. 3, lines 17-39; col. 4, lines 6-16). This teaching states that phosphatidylcholine and cholesterol can be included in the liposome preparation and that particles routinely have a size of 25 nm to 500 nm. It was also stated that suitable HIV immunogens could be included in such compositions.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to prepare liposomal compositions, as taught by Alving and Glenn (1999), containing the modified HIV-1 Env described by Lavallée and Thibodeau (1996), since this would provide a composition that would be useful for generating immunological reagents against the modified Env. Such reagents would prove useful in a wide variety of applications including biochemical, diagnostic, and immunological.

Claims 21 and 22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lavallée and Thibodeau (1996) in view of Alving and Glenn (1999), and further in view of Mannino and Goodman-Snitkoff (2000). Mannino and colleague disclose the preparation of liposomes comprising peptide-lipid conjugates that are similar in structure to the liposomes described by Alving and Glenn. The former inventors report (see col. 13, lines 46-53) that suitable oral and mucosal formulations can be prepared using techniques that are well-known in the prior art. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to prepare liposomal compositions comprising a modified HIV-1 Env, as suggested by Lavallée and Thibodeau (1996) and Alving and Glenn (1999), *supra*, that are suitable for oral or mucosal administration, as taught by Alving and Glenn (1999), since this would provide the skilled artisan with an immunogenic composition that can be administered to multiple sites, depending upon the need.

Correspondence

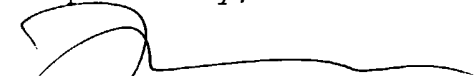
Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 9:30 AM to 7:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (571) 272-0910 or (571) 272-0902, respectively. Direct general inquiries to the Technology Center 1600 receptionist at (571) 272-1600.

Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further

Serial No.: 09/632,806
Applicants: Thibodeau, L., and C. Lavallee

guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Respectfully,

A handwritten signature in black ink, appearing to read "Jeffrey S. Parkin", with a long horizontal flourish extending to the right.

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

09 July, 2004